Modified PTO/SB/33 (10-05)

PRE-APPEAL BRIEF REQUEST FOR REVIEW	Docket Number Q116808	
Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number 10/568,761	Filed February 21, 2006
	First Named Inventor Takamasa WATANABE	
	Art Unit 1644	Examiner HADDAD, MAHER M

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Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal

The review is requested for the reasons(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

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March 9, 2010
Date

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Takamasa WATANABE, et al.

Docket No: Q116808

Appln. No.: 10/568,761

Group Art Unit: 1644

Confirmation No.: 6669

Examiner: HADDAD, MAHER M

Filed: February 21, 2006

For: PREVENTIVE OR REMEDY FOR INFLAMMATORY BOWEL DISEASES CONTAINING ANTI-CD81 ANTIBODY AS THE ACTIVE INGREDIENT

PRE-APPEAL BRIEF REQUEST FOR REVIEW

MAIL STOP AF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Pre-Appeal Brief Conference Pilot Program, and further to the Final Office Action dated September 9, 2009, and the Advisory Action dated February 22, 2010, Applicants file this Pre-Appeal Brief Request for Review. This Request is also accompanied by the filing of a Notice of Appeal.

Applicants now turn now to the rejections for which review is requested:

The Rejection of Claims 19, 20, 31, 32 and 35 Under 35 U.S.C. § 102(b)

1. On page 2 of the Office Action, Claims 19, 20, 32 and 35 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Fleming *et al.* (U.S. Patent No. 6,423,501).[1] In the rejection, the Examiner contends that Fleming *et al.* teaches a method for treating inflammatory bowel disease in a subject, comprising administering anti-CD81 antibodies to such

[1] Claims 19, 20, 32 and 35 are also rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 98/25647. As WO 98/25647 and Fleming *et al.* share the same disclosure, this rejection is in error for the same reasons discussed with respect to Fleming *et al.* See page 8 of the Reponse filed February 10, 2010.

subject. See page 2, paragraph 7, of the Office Action mailed September 9, 2009. Having alleged that Fleming *et al.* teaches the claimed method, the Examiner asserts that "[a]ccordingly, the '501 patent is enabled for how to make and use … anti-CD81-antibodies in [the] treat[ment of] IBD." See page 2, final paragraph, of the Advisory Action mailed February 22, 2010.

For the following reasons, the rejection is in clear error and should be withdrawn.

Applicants have pointed out, on the record, the proper legal standard for anticipation. See page 3, 3rd full paragraph, of the Response filed February 10, 2010; anticipation is only proper if, in a single prior art reference, each and every element of the claimed invention is disclosed, and arranged as in the claim. *Net MoneyIn, Inc. v. Verisign, Inc.*, 2008 U.S. App. LEXIS 21827, 1, 27 (Fed. Cir. 2008). The court in *Verisign*, quoting *In re Arkley*, 455 F.2d 586 (C.C.P.A. 1972), held that for anticipation, "[t]he prior art reference must *clearly and unequivocally* disclose the claimed invention or direct those skilled in the art to the invention without any need for picking, choosing, and combining various disclosures not **directly** related to each other by the teachings of the cited reference." (Emphasis added.)

However, in maintaining the rejection, the Examiner picks and chooses amongst a variety of distinct and alternative embodiments of Fleming *et al.*, which embodiments are not *directly* related to each other, in an attempt to find anticipation; for example, from column 13, lines 34-45, inflammatory bowel disease is specifically chosen from a plethora of distinct and alternative diseases, and this embodiment is combined with antibodies against anti-CD81, which are specifically chosen from column 9, line 65, to column 10, line 3; however, at no point does Fleming *et al.* disclose Applicants' specific combination of claim elements in a single source, or provide any teaching *directly* relating them to one another so as to avoid the need for impermissibly picking and choosing amongst these alternative and distinct embodiments. Applicants submit that, in violation of the standard articulated in *Arkley*, such piecing together, in the absence of any direct relationship linking them together to prevent picking and choosing, does not represent disclosure of the claimed invention "as arranged in the claim," and thus does not constitute anticipation.

To hold otherwise is to submit that disclosure of a vast genus of diseases, when combined with an accompanying disclosure of a similarly vast genus of agents, anticipates every possible combination of species that can be selected from these genera; however, Applicants submit that the mere generic disclosures of Fleming *et al.*, on which the instant rejection is based, do not

constitute disclosure with "sufficient specificity" to establish anticipation. It is well-settled that "a prior art reference that discloses a genus still does not inherently disclose all species within that broad category." *Metabolite Laboratories, Inc. v. Laboratory Corporation of America,* citing *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262 (Fed. Cir. 1989). The relied-upon portions of Fleming *et al.* merely disclose broad genera of diseases and agents; Fleming *et al.* lacks any teachings to *directly* relate the specific species together as arranged as in the instant claims without picking and choosing, nor is there any pattern of preferences that would serve to narrow the number of possible embodiments to a small number of species so that one of skill in the art would have "at once envisaged" Applicants' claimed invention from these broad genera. See *In re Petering*, 301 F.2d 676 (C.C.P.A. 1962). Moreover, as a matter of law, Applicants' specifically claimed method does not inherently flow from the generic disclosures in Fleming *et al.*; inherent disclosure does not negate the requirement that the selected elements be disclosed with sufficient specificity in the same way as arranged in the claim without any need for picking and choosing. See page 5, 1st full paragraph, of the Response filed February 10, 2010.

Thus, Fleming *et al.* does not teach the presently claimed invention, and thus the rejection is in clear error.

Moreover, to anticipate, the reference must enable the claimed invention; Applicants submit that the reasons proffered by the Examiner in an attempt to establish that Fleming *et al.* enables the presently claimed invention are in clear error. First, the Examiner purports that Fleming *et al.* anticipates because "a patent is an enabling reference for all that it teaches." Applicants have previously noted why this reasoning is unsound. See the paragraph bridging pages 5 and 6 of the Response filed February 10, 2010. Second, the rejection is predicated on the allegation that Fleming *et al.* is enabling, and anticipatory, because it does place "the public ... in possession of the claimed subject matter ... [t]he reason [being] that [although] section 112 'provides that the specification must enable one skilled in the art to 'use' the invention[,] ... section 102 makes no such requirement as to an anticipatory disclosure." Applicants have also noted why this reasoning is unsound. See the paragraph bridging pages 6 and 7 of the Response filed February 10, 2010. As previously pointed out by Applicants, Fleming *et al.* fails to enable one of skill in the art to practice the presently claimed method, at least because one of skill in the art would have had to embark on undue experimentation to connect antibody binding to CD81 as

a treatment for inflammatory bowel disease amongst the myriad of other diseases recited by Fleming *et al.* As Applicants have previously noted on the record, as a result of such, Fleming *et al.* does not place those of skill in the art, in the absence of extensive and undue experimentation, in possession of the claimed invention, as is required to sustain the rejection. See page 4, 1st full paragraph, of the Amendment filed July 30, 2009. Withdrawal of the rejection is respectfully requested.

2. On page 5 of the Office Action, Claims 19, 20, 31, 32 and 35 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Curd *et al.* (WO 00/67796). The Examiner contends that Curd *et al.* teaches a method for treating inflammatory bowel diseases, comprising administering an anti-CD81 antibody, citing Claims 1, 2, 3, 6 and 7.

For the following reasons, the rejection is in clear error and should be withdrawn.

Curd *et al.* fails as an anticipatory reference for essentially the same reasons as Fleming *et al.*; the Examiner cites to Claims 1, 2, 3, 6 and 7 in an attempt to disclose the claimed invention. Claim 2 encompasses a vast genus of alternative and distinct B-cell surface antigens, and Claim 6 recites a vast genus of alternative and distinct diseases that may be treated by antagonism of a B-cell surface antigen. Claims 2 and 6 also recite a plethora of alternative and distinct embodiments. However, at no point does Curd *et al.* disclose Applicants' specific combination of claim elements in a single source, or provide any teaching *directly* relating them to one another so as to avoid the need for impermissibly picking and choosing amongst these alternative and distinct embodiments. Applicants submit that, in violation of the standard articulated in *Arkley*, the rejection is premised on picking and choosing a specific B-cell antigen from one claim, and a specific disease from another, in the absence of any teachings to *directly* relate the specific B-cell antigen and disease together as arranged as in the instant claims without picking and choosing. Nor is there any pattern of preferences that would serve to narrow the number of possible embodiments to a small number of species so that one of skill in the art would have "at once envisaged" Applicants' claimed invention from these broad genera. Moreover, Applicants have pointed out why Curd *et al.* fails as an anticipatory reference also because it fails to enable the presently claimed method. See page 10, 1st full paragraph, of the Response filed February 10, 2010. Thus, Curd *et al.* does not teach the presently claimed

invention, and thus the rejection is in clear error. Withdrawal of the rejection is respectfully requested.

The Rejection of Claims 31, 33 and 34 Under 35 U.S.C. § 103(a)

On page 6 of the Office Action, Claims 31, 33 and 34 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fleming *et al.* (U.S. Patent No. 6,423,501), WO 98/25647 or WO 00/67796, in view of Owens *et al.*, of record. The Examiner relies upon Fleming *et al.*, WO 98/25647 and WO 00/67796 for the same reasons as in the anticipation rejections discussed above.

For the following reasons, the rejection is in clear error and should be withdrawn.

As previously noted on the record, and as discussed above, neither Fleming *et al.*, WO 98/25647 nor WO 00/67796 disclose, expressly or inherently, a method of improving or treating inflammatory bowel disease comprising administering an anti-CD81 antibody to a patient in need thereof, and there exists nothing in these references that would incite any expectation of success in performing such a method. Owens *et al.* fails to rectify this deficiency. See page 11 of the Response filed February 10, 2010. Thus, even assuming *arguendo* these references were combined, those of ordinary skill in the art would not arrive at the presently claimed invention. Withdrawal of the rejection is respectfully requested.

Respectfully submitted,

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